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SPECIAL ARTICLE

Statement on matching language to the type of evidence used in describing observational studies vs. randomized trials

Editors of the Heart Group Journals*

The Zurich Heart House, Moussonstrasse 4, CH-8091 Zurich, Switzerland

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See page 7 for the editorial comment on this article (doi:10.1093/eurheartj/ehs387)

Observational studies and randomized controlled trials (RCTs) provide different types of evidence for the evaluation of a therapeutic intervention. Each has advantages and disadvantages. As illustrated in a series of examples in a separate review,[1] interpretation of observational studies, which are relatively descriptive, can be confounded and rendered ambiguous by the fact that many variables impacting outcomes can differ between groups. Therefore, such studies cannot necessarily establish causality. When RCTs are performed using standard design characteristics, the intervention under study is the only variable that differs between the groups. As such, RCTs are much better suited to establish causality in the specific population studied than observational studies.

Therefore, it is important to carefully select the language used to report each type of study in order to foster the most accurate data interpretation by the reader. The Editors of the Heart Group (representing the world's cardiovascular journals) recommend that all investigators and editors carefully select language to 'match' the type of study conducted (observational vs. randomized) without overstating findings or drawing erroneous conclusions about causality when they cannot be rigorously established.

As an illustrative example, when reporting results from an observational study that shows fewer deaths in one arm than in another, one should use descriptive statements such as, 'the intervention is associated with lower mortality', rather than definitive statements such as 'the intervention reduces mortality' or 'the intervention results in fewer deaths'. Conversely, when reporting the results of a RCT, in which the only difference between the groups is the intervention, it is appropriate to use declarative statements such as 'the intervention reduced risk'. Additional language matched with the corresponding study type is listed in *Table 1*.

Although the differences in language may be subtle, their implications are important, since they can suggest that a causal relationship exists when such a relationship has not been established. Thus, all manuscripts should be written and edited not only for scientific

Table 1 Table of suggested language based on study type

Type of language	Randomized trial	Observational study
Descriptive statements	'reduced the risk by'	'a lower risk was observed' 'there is a relationship' 'there is an association'
Descriptive nouns	'relative risk reduction' 'benefit'	'difference in risk' 'risk ratio'
Verbs	'affected' 'caused' 'modulated risk' 'treatment resulted in' 'reduced hazard'	'correlates with' 'is associated with'
Incorrect terms/avoid using		'reduced risk' (active verb) 'lowered risk' (active verb) 'benefit'

With permission from Kohli and Cannon.[1]

* Christopher P. Cannon is the corresponding author. Tel: +1 617 278 0146, Fax: +1 617 734 7329, Email: cpcannon@partners.org

accuracy, but also for appropriateness of language used in describing the level of evidence provided by the study.

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Reference

1. Kohli P, Cannon CP. The importance of matching language to type of evidence: avoiding the pitfalls of reporting outcomes data. *Clin Cardiol* 2012. doi:10.1002/clc.22066, (in press).

CARDIOVASCULAR FLASHLIGHT

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Surgical recycling of a percutaneously implanted Melody valve

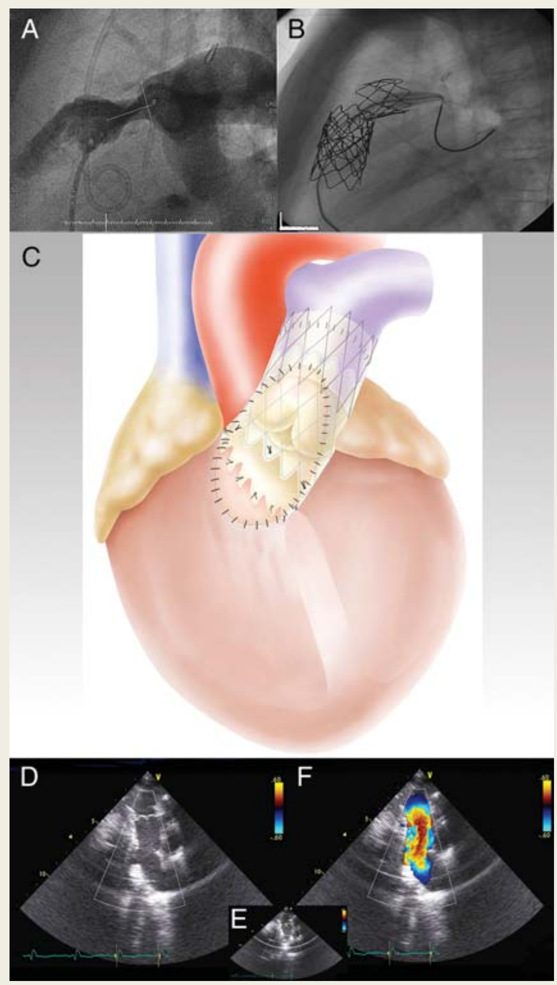
Hitendu Dave[1]*†, Oliver Kretschmar[2]†, and René Prêtre[1]

[1]Division of Congenital Cardiovascular Surgery, University Children's Hospital Zurich; and [2]Division of Paediatric Cardiology, University Children's Hospital Zurich, Steinwiesstrasse 75, 8032, Zurich, Switzerland

* Corresponding author. Tel: +41 44 2668002, Fax: +41 44 2668021, Email: hitendu.dave@kispi.uzh.ch; hitendu@hotmail.com

† These authors contributed equally.

A child corrected for pulmonary atresia and VSD (Fallot type) during infancy underwent a conduit change done with a 18-mm Contegra (Medtronic Inc., USA) at 7.5 years of age. She needed stenting, pre-stenting and eventually, Melody (Medtronic Inc.) valve implantation for supravalvar conduit stenosis 3 months after implantation (*Panel A*). During withdrawal of the sheath, the pre-stent and the Melody construct dislodged into the right ventricle (RV) (*Panel B*) because of the softness of the newly implanted conduit, necessitating an emergent operation. After carrying out cardiopulmonary bypass, the right ventricular outflow tract (RVOT) was slit open on an empty beating heart and the dislodged Melody valve was fished out and noted to be in good condition. The distal stent covered the distal stenosis adequately and held it open and hence was left *in situ*. The Melody valve (in a crimped position) was placed stretching the whole course of the conduit and balloon dilated to 20 mm (*Panel C*). The proximal struts (posteriorly and laterally) of the Melody were bent to conform to the RV-Conduit transition and suture fixed to prevent migration. The RVOT was closed with a Xenopericardial patch and the proximal struts (anteriorly) sutured to it (*Panel C*). The patient was extubated 10 h after the surgery and discharged after 14 days. The Melody valve showed good function with trivial regurgitation (*Panels D–F*). At 1 year the peak/mean gradient was 30/9 mm Hg with trivial regurgitation, normal RV size, and normal biventricular function. 'Recycling' of the Melody valve saved on cost and avoided a full-blown emergent conduit change operation and a potential stenotic process by preventing a circular anastomosis. This procedure has inadvertently opened doors for surgical insertion of a nearly 'Sutureless' biological valve in pulmonary position in children, with the possibility of subsequent percutaneous balloon dilatation.



Panel A. Long segment supravalvar Contegra stenosis.

Panel B. Dislodged pre-stent and Melody construct into the RV cavity; the distal stent remains *in situ*.

Panel C. Surgically anchored Melody valve. The distal stent treating the supravalvar stenosis was left *in situ*.

Panel D–F. Postoperative 2D echo and colour Doppler images of a well-functioning Melody valve.